

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,	)
	)
Plaintiff,	)
	) C.A. No. 20-125 (LPS)
v.	) (CONSOLIDATED)
	)
ARCHERDX, INC., ARCHERDX, LLC and	) <b>REDACTED –</b>
INVITAE CORP.,	) <b>PUBLIC VERSION</b>
	)
Defendants.	)

**NATERA, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY  
JUDGMENT AND TO PRECLUDE CERTAIN EXPERT TESTIMONY**

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## Table of Contents

I.	PARTIAL SUMMARY JUDGMENT IS WARRANTED .....	1
A.	Defendants' Prosecution Laches Defense Fails As A Matter Of Law .....	1
1.	Defendants Fail to Show Any Evidence of Delay, Much Less Unreasonable and Unexplained Delay, In Natera's Prosecution of the cfDNA Patents .....	1
2.	Defendants Fail to Demonstrate Any Prejudice or Intervening Rights.....	3
B.	Defendants Unclean Hands Defense Fails As A Matter Of Law.....	6
C.	Defendants Have Failed To Demonstrate Inequitable Conduct .....	7
1.	No Inequitable Conduct Based on Correction of Inventorship .....	7
2.	No Inequitable Conduct Based on Alleged Failure to Disclose Litigation Documents to the PTO .....	9
D.	Defendants Have Failed To Establish Invalidity Based On Improper Inventorship .....	12
E.	The Asserted Patents Claim What The Applicants Regarded As Their Inventions .....	16
F.	The Asserted Claims Of The '708, '814 And '220 Patents Are Not Indefinite .....	17
1.	The '708 Patent Claims Are Not Indefinite .....	17
2.	The Claim Term "Sequencing Tag" Does Not Render the Asserted '814 and '220 Patents Indefinite .....	20
II.	DAUBERT MOTION ARGUMENTS.....	22
A.	Mr. Kelley's Prosecution Laches Opinions Should Be Excluded In Its Entirety.....	22
B.	Dr. Cooper's Inventorship Opinions Should Be Excluded In Its Entirety.....	24
III.	CONCLUSION.....	25

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.</i> , 607 F.3d 817 (Fed. Cir. 2010).....	8
<i>Allergan, Inc. v. Teva Pharms. USA, Inc.</i> , No. 2:15-CV-1455-WCB, 2017 WL 1512334 (E.D. Tex. Apr. 27, 2017) .....	12
<i>Ancora Techs. Inc. v. Apple, Inc.</i> , 744 F.3d 732 (Fed. Cir. 2014).....	17
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986).....	7
<i>Apator Miitors APS v. Kampstrup A/S</i> , 887 F.3d 1293 (Fed. Cir. 2018).....	25
<i>Auxilium Pharms., Inc. v. Watson Labs., Inc.</i> , No. CIV.A. 12-3084 JLL, 2014 WL 9859224 (D.N.J. Dec. 16, 2014) .....	12
<i>The Barbed-Wire Patent</i> , 143 U.S. 275, 284 (1892) .....	15
<i>Bayer Cropscience AG v. Dow Agrosciences LLC</i> , No. 1:10-CV-1045, 2012 WL 1253047 (D. Del. Apr. 12, 2012).....	11
<i>Beriont v. GTE Labs. Inc.</i> , 601 Fed. Appx. 937 (Fed. Cir. 2015).....	15
<i>Bos. Sci. Corp. v. Johnson &amp; Johnson</i> , 550 F. Supp. 2d 1102 (N.D. Cal. 2008) .....	12
<i>Celotex Corp. v. Catrett</i> , 477 U.S. 317 (1986).....	6
<i>Cordance Corp. v. Amazon.com</i> , 631 F. Supp. 2d 484 (D. Del. 2009).....	<i>passim</i>
<i>Drone Techs., Inc. v. Parrot S.A.</i> , 838 F.3d 1283 (Fed. Cir. 2016).....	12
<i>Egenera, Inc. v. Cisco Systems, Inc.</i> , 972 F.3d 1367 (Fed. Cir. 2020).....	8, 12, 24
<i>F'Real Foods, LLC v. Hamilton Beach Brands, Inc.</i> , No. 16-41-CFC, 2019 WL 1747550 (D. Del. Apr. 18, 2019).....	9

<i>Finnigan Corp. v. United States Int'l Trade Comm'n,</i> 180 F.3d 1354 (Fed. Cir. 1999).....	14
<i>Fiskars, Inc. v. Hunt Mfg. Co.,</i> 221 F.3d 1318 (Fed. Cir. 2000).....	11
<i>Gilead Scis., Inc. v. Merck &amp; Co.,</i> 888 F.3d 1231 (Fed. Cir. 2018).....	7
<i>Hess v. Advanced Cardiovascular Sys. Inc.,</i> 106 F.3d 976 (Fed. Cir. 1997).....	13
<i>Hyatt v. Hirshfeld,</i> 998 F.3d 1347 (Fed. Cir. 2021).....	3
<i>Kingsdown Medical Consultants, Ltd. v. Hollister Inc.,</i> 863 F.2d 867 (Fed. Cir. 1988).....	4
<i>Liebel-Flarsheim Co. v. Medrad, Inc.,</i> 358 F.3d 898 (Fed. Cir. 2004).....	4
<i>Lucent Techs., Inc. v. Microsoft Corp.,</i> 544 F. Supp. 2d 1080 (S.D. Cal. 2008).....	6
<i>Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.,</i> No. CV 07-127-LPS-MPT, 2014 WL 547712 (D. Del. Feb. 7, 2014) .....	12
<i>Malico Inc. v Cooler Master USA,</i> No. C 11-4537-RS, 2013 WL 4482503 (N.D. Cal. 2013) .....	14
<i>Medichem, S.A. v. Rolabo, S.L.,</i> 437 F.3d 1157 (Fed. Cir. 2006).....	25
<i>MorphoSys AG v. Janssen Biotech, Inc.,</i> 358 F. Supp. 3d 354 (D. Del. 2019).....	15, 22
<i>Ohio Willow Wood Co. v. Alsp S., LLC,</i> 735 F.3d 1333 (Fed. Cir. 2013).....	8
<i>Pannu v. Iolab Corp.,</i> 155 F.3d 1344 (Fed. Cir. 1998).....	8
<i>Personalized Media Commc'ns, LLC v. Apple, Inc.,</i> No. 2:15-cv-01366-JRG, 2021 WL 3471180 (E.D. Tex. Aug. 5, 2021) .....	4
<i>Plastipak Packaging, Inc. v. Premium Waters, Inc.,</i> No. 20-CV-098-WMC, 2021 WL 3675151 (W.D. Wis. Aug. 19, 2021) .....	12

<i>Pro-Mold &amp; Tool Co. v. Great Lakes Plastics,</i> 75 F.3d 1568 (Fed. Cir. 1996).....	8
<i>Purewick Corp. v. Sage Prods., LLC,</i> No. 19-1508, 2021 WL 2593338 (D. Del. June 24, 2021) .....	22, 23, 24
<i>Sanofi-Aventis v. Advancis Pharmaceutical Corp.,</i> 453 F. Supp. 2d 834 (D. Del. 2006).....	6
<i>Solomon v. Kimberly-Clark Corp.,</i> 216 F.3d 1372,1380 (Fed. Cir. 2000).....	15, 17, 21
<i>Sonos, Inc. v. D&amp;M Holdings, Inc.,</i> 297 F. Supp. 3d 501 (D. Del. 2017).....	22
<i>Stambler v. RSA Security, Inc.,</i> 243 F. Supp. 2d 74 (D. Del 2003).....	1, 2
<i>Stark v. Advanced Magnetics, Inc.,</i> 119 F.3d 1551 (Fed. Cir. 1997).....	8
<i>Symbol Tech., Inc. v. Lemelson Med. Educ. &amp; Rsch. Found.,</i> 422 F.3d 1378 (Fed. Cir. 2005).....	1, 2
<i>Therasense, Inc. v. Becton, Dickinson &amp; Co.,</i> 649 F.3d 1276 (Fed. Cir. 2011).....	9, 12
<i>Trovan, Ltd. v. Sokymat SA,</i> 299 F.3d 1292 (Fed. Cir. 2002).....	15
<i>Univ. of Colorado Foundation, Inc. v. Am. Cyanamid Co.,</i> 342 F.3d 1298 (Fed. Cir. 2003).....	15
<i>Webster Elec. Co. v. Splitdorf Elec. Co.,</i> 264 U.S. 463 (1924).....	3
<i>Westphal v. Fawzi,</i> 666 F.2d 575 (C.C.P.A. 1981) .....	2
<i>Woodbridge v. United States,</i> 263 U.S. 50 (1923).....	4
<i>XpertUniverse, Inc. v. Cisco Sys., Inc.,</i> No. 09-157-RGA, 2013 WL 867640 (D. Del. Mar. 8, 2013) .....	13
<b>Statutes</b>	
35 U.S.C. § 256(b).....	8

**Other Authorities**

Fed. R. Civ. P. 30(b)(6).....	5, 7
Fed. R. Civ. P. 56(c) .....	9, 16

## I. PARTIAL SUMMARY JUDGMENT IS WARRANTED

### A. DEFENDANTS' PROSECUTION LACHES DEFENSE FAILS AS A MATTER OF LAW

Holding a patent unenforceable for prosecution laches is exceptionally rare as it requires “an unreasonable and unexplained delay in prosecution” that constitutes “*egregious cases of misuse of the statutory patent system.*” *Symbol Tech., Inc. v. Lemelson Med. Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) (emphasis added). Defendants have failed to make this showing.

#### 1. Defendants Fail to Show Any Evidence of Delay, Much Less Unreasonable and Unexplained Delay, In Natera's Prosecution of the cfDNA Patents

As set forth in Natera’s opening brief, Natera diligently prosecuted the entire family of related patents, including the asserted cfDNA Patents. Defendants do not dispute that there was no delay in Natera’s prosecution of the asserted cfDNA Patents or the related patents but contend that Natera delayed “until 2019 to present the challenged claims for prosecution.” D.I. 441, 37. Defendants’ argument ignores the indisputable fact that Natera was prosecuting an additional 13 applications in the same family, 6 of which issued as patents, during the period of alleged delay.<sup>1</sup> D.I. 432, Sections III.A, IV.A.1. Indeed, courts have declined to hold patents unenforceable for prosecution laches on similar facts. *Cordance Corp. v. Amazon.com*, 631 F. Supp. 2d 484, 491 (D. Del. 2009); *Stambler v. RSA Security, Inc.*, 243 F. Supp. 2d 74, 76 (D. Del 2003)). Defendants’

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<sup>1</sup> Defendants argue Natera “obtained just 3 patents in the cfDNA patent family” during the period of alleged delay. D.I. 441, 41. Not so. As stated on the face of the asserted cfDNA Patents, 6 of the 13 additional applications Natera was prosecuting issued as patents: (1) Application No. 14/918,544 filed on Oct. 20, 2015 issued as U.S. Patent No. 10,316,362; (2) Application No. 14/692,703 filed on Apr. 21, 2015 issued as U.S. Patent No. 10,179,937; (3) Application No. 14/538,982 filed on Nov. 24, 2014 issued as U.S. Patent No. 9,677,118; (4) Application No. 13/335,043 filed on Dec. 22, 2011 issued as U.S. Patent No. 10,113,196; (5) Application No. 13/300,235 filed on Nov. 18, 2011 issued as U.S. Patent No. 10,017,812; and (6) Application No. 13/110,685 filed on May 18, 2011 issued as U.S. Patent No. 8,825,412. D.I. 432, 4-5, Exs. 1-4.

attempt to distinguish *Cordance* and *Stambler* falls flat. Defendants argue that in those cases, the patent owner was busy prosecuting other applications. D.I. 441, 40-41. So was Natera. D.I. 432, Sections III.A, IV.A.1. If anything, Defendants' argument supports summary judgment of no prosecution laches.

Whether claims are *presented* right away or 7-8 years after the filing of a priority application does not give rise to a priori assumptions of prosecution laches without a showing of “unreasonable delay” which may be triggered based on the “overall delay in *issuing* claims.” *Symbol Techs., Inc.*, 422 F.3d at 1386 (“*Symbol III*”) (emphasis added). In *Symbol III*, the Federal Circuit provided examples of both reasonable and unreasonable delay and noted that an applicant could reasonably “refile an application” where “such refiling is not unduly successive or repetitive.” *Id.* at 1385. Here, Natera’s prosecution of the entire family of related patents, including the asserted cfDNA Patents, bears no resemblance to the Federal Circuit’s example of “unreasonable delay” involving “refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance.” *Id.* And the PTO evaluated the later submitted claims of the asserted cfDNA Patents “for support in the original disclosure” and raised no objections under Section 112 or prosecution laches grounds. *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981). *Symbol III* and *Westphal* dispose of Defendants’ “late presentation” argument.

Defendants rely on two cases that are factually distinguishable. D.I. 441, 37-38 (citing *Webster* and *Hyatt*). First, the pre-GATT 1924 *Webster* case involved an interference and amendment to a divisional application eight years and four months after the filing of the original application “and three years after the commencement of the present suit” extending the term of the asserted patents, and an admission by the inventor that he intentionally failed to present the

new claims in the original application. *Webster Elec. Co. v. Splitdorf Elec. Co.*, 264 U.S. 463, 464-466 (1924). Here, no patent term has been extended and there is no evidence of intentional delay. Similarly, the egregious conduct in *Hyatt* has no similarity to the facts here. *Hyatt* involved a “pattern of delay in prosecuting...nearly 400 patent applications from 1969 through the present day,” “claiming priority to applications more than 45 years old” such that “*Hyatt*’s inventions were submerged,” and “bulk-filing about 400 photocopies of 11 applications in the days before the U.S.’s patent term changed on June 8, 1995” with many of the claim set “identical to each other.” *Hyatt v. Hirshfeld*, 998 F.3d 1347, 1354-1356 (Fed. Cir. 2021). Nothing remotely resembling these egregious fact patterns exist here.

Importantly, both *Webster* and *Hyatt* involved pre-GATT applications for which the then 17-year patent term would begin from the issuance of the patents, and hence delay in patent filing would effectively extend the patent term. In contrast, the applications that issued as the cfDNA Patents were filed post-GATT, where the 20-year patent term starts from the filing date of the earliest priority application, and therefore, delay in patent filing would not extend the life of the patent. In fact, the *Hyatt* court noted the exceedingly rare success of the prosecution laches defense explaining that in the nearly 80 years after *Webster*, it has only been affirmed in two instances (*i.e.*, the 2002 *Bogese* and 2005 *Symbol Tech.* cases), both of which involved pre-GATT applications. *Id.* at 1361.

Simply put, even with inferences drawn in their favor, Defendants have not shown any delay by Natera in prosecuting the cfDNA Patents, let alone any delay that was unreasonable and inexcusable that constitutes an *egregious misuse of the statutory patent system* on this record. Their prosecution laches defense fails as a matter of law at the first prong.

## **2. Defendants Fail to Demonstrate Any Prejudice or Intervening Rights**

Defendants were on notice of Natera’s inventions at least as of October 2012 when the

priority application published and knew about Natera’s patenting activity in the general area. D.I. 432, Section IV.A.2. It is legally irrelevant whether Natera was aware of or “monitoring” Defendants’ multiplex PCR technology around 2014, as Defendants allege. D.I. 441, 38-39. Defendants do not dispute that it is black letter law that “there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor’s product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor’s product the applicant’s attorney has learned about during the prosecution of a patent application.” *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988); *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 n.2 (Fed. Cir. 2004). In *Cordance*, Amazon, like Defendants here, argued that Cordance was monitoring Amazon’s products and “kept its invention hidden from the world.” 631 F. Supp. 2d at 489, 492. The court rejected these arguments explaining “similar considerations regarding the exercise of plaintiff’s patent rights and the effect on a competitor and the market noted by the *Intuitive Surgical* court were insufficient to establish prosecution laches” and granted Cordance summary judgment motion of no prosecution laches. *Id.* at 492.

Defendants cite two cases involving prosecution of pre-GATT patent applications where there was clear evidence that the patent owner intentionally engaged in prosecuting patents serially to significantly delay issuance of its patents with a strategy of prolonging patent coverage as long as possible. D.I. 441, 43 (citing *Woodbridge v. United States*, 263 U.S. 50, 57 (1923) and *Personalized Media Commc’ns, LLC v. Apple, Inc.*, No. 2:15-cv-01366-JRG, 2021 WL 3471180, at \*21 (E.D. Tex. Aug. 5, 2021)). Again, nothing like these egregious fact patterns is present here, and the distinction between pre- and post-GATT patent applications is significant: Natera, unlike the patent owner in *Woodbridge* and *Personalized Media Commc’ns*, had no incentive, but rather

a disincentive, to delay its patent application and reduce the effective term of its own patents – something Defendants never even address.

Moreover, Defendants fail to offer any evidence to demonstrate that they would have done anything differently. Defendants' attempt to trivialize their designated corporate witness's testimony on this topic lacks merit. Mr. Stahl was the Chief Operating Officer and Chief Scientific Officer of Defendant ArcherDX and is currently the President of Oncology at Defendant Invitae. D.I. 441, 42. Further, Mr. Stahl was Defendants' designated Rule 30(b)(6) witness on the topic of "Defendants' knowledge of facts relating to whether Natera delayed unduly in the prosecution of the Asserted Patents and any prejudice to Defendants."<sup>2</sup> Under Rule 30(b)(6), his admissions are binding on Defendants.

Mr. Stahl admitted that Defendants have "known about Natera since at least 2016" and would not "have changed anything" in terms of its R&D, product development, or commercialization had it known that Natera would be asserting its patents against Defendants; this is not mere "speculation." D.I. 432, 10-11. Mr. Stahl's testimony underscores Defendants' failure to meet their burden of proving prejudice or intervening rights. Defendants knew of Natera's intellectual property and admitted they would not have done anything different. Summary judgment is mandated "against a party who fails to make a showing sufficient to establish the

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<sup>2</sup> Defendants designated Mr. Stahl as their Rule 30(b)(6) witness on a number of topics, including (1) Defendants' knowledge of facts relating to whether Natera delayed unduly in the prosecution of the Asserted Patents and any prejudice to Defendants (Topic 48); (2) All efforts by Defendants or on their behalf to monitor Natera's diagnostic cfDNA-based testing (Topic 32); and (3) the date and factual circumstances underlying when Defendants first became aware of the Asserted Patents or any application from which any Asserted Patent claims priority, including the date, circumstances, persons involved and steps taken, if any, to investigate whether any of Defendants' Accused Products infringe the Asserted Patents (Topic 33). D.I. 196; Ex. 36, 9/3/2021Stahl Tr., 73:21-74:11 (Defendants' counsel confirmed Mr. Stahl was designated on Topics "1 through 5, 12, 13, 19, subject to specific responses, 23, 24, 26, 28, 30, 33, 36, 38, 39, 41, 43, 44, and then also 32 and 48").

existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

#### **B. DEFENDANTS UNCLEAN HANDS DEFENSE FAILS AS A MATTER OF LAW**

Defendants perfunctorily raise two theories of unclean hands in their opposition brief: (1) a recast of their argument that Natera allegedly “delayed for nearly a decade in presenting its claims for prosecution;” and (2) “suspect events” arising from a Natera employee, Ms. Giorda, who allegedly gained access to confidential information relating to ArcherDX’s products in development during her employment at ArcherDX and then returned to Natera shortly thereafter. D.I. 441, 44. Both theories fail as a matter of law.

Defendants’ first theory is premised on the same arguments underlying their prosecution laches defense and fails for the same reasons. Simply put, Defendants have not only failed to adduce “clear, convincing and unequivocal evidence that would reasonably support a finding of unclean hands,” but have also failed to adduce any evidence whatsoever of the required “bad intent” that is the “essence of unclean hands” with respect to Natera’s lawful prosecution practice. *Sanofi-Aventis v. Advancis Pharmaceutical Corp.*, 453 F. Supp. 2d 834, 856-857 (D. Del. 2006); *Lucent Techs., Inc. v. Microsoft Corp.*, 544 F. Supp. 2d 1080, 1100 (S.D. Cal. 2008); *see also* D.I. 432, Sections IV. A and IV. B.

Defendants’ second theory fares no better. Defendants’ opposition advances no evidence to support a claim that Natera somehow improperly gained access to Defendants’ confidential information through Ms. Giorda. The reason is simple – there is none.<sup>3</sup> In fact, Mr. Stahl,

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<sup>3</sup> Indeed, Defendants knew full well that this defense would not withstand scrutiny. They never even attempted to subpoena Ms. Giorda or asked one question of Natera’s witnesses about any alleged access to Archer confidential information during the lengthy depositions.

Defendants' 30(b)(6) witness who was "prepared" to testify on this topic<sup>4</sup>, admitted that he didn't "believe that -- that anything was found" with respect to Natera allegedly having "taken any confidential information." D.I. 432, 14. Defendants' conclusory assumptions based on unspecified "suspect events" are not "reasonable" and fall far short of supporting a defense of unclean hands. D.I. 441, 44. *See Cordance*, 631 F. Supp. 2d at 488 (the non-moving party with the burden of proof "may not rest upon the mere allegations or denials of his pleadings, but must set forth specific facts showing that there is a genuine issue for trial.") (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

The facts here bear no resemblance to the *Gilead* case that Defendants rely on. *Id.* at 44-45. In *Gilead*, the court was presented with detailed evidence of business misconduct – both documentary and deposition testimony – establishing that Merck had violated a clear "firewall" understanding between the parties that was further enforced through a non-disclosure agreement and improperly influenced related patent prosecutions. *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1240-1244 (Fed. Cir. 2018). There is no such evidence here – as even Defendants' Rule 30(b)(6) witness admitted. D.I. 432, 14. Summary judgment of no unclean hands is proper.

### C. DEFENDANTS HAVE FAILED TO DEMONSTRATE INEQUITABLE CONDUCT

#### 1. No Inequitable Conduct Based on Correction of Inventorship

Defendants have failed to adduce clear and convincing evidence of but-for materiality and intent to the deceive the PTO. *Ohio Willow Wood Co. v. Alsp S., LLC*, 735 F.3d 1333, 1345 (Fed.

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<sup>4</sup> Defendants designated Mr. Stahl as their Rule 30(b)(6) witness on Topic 50, "[Defendants'] knowledge of facts relating to whether Natera filed its patent applications only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX's Accused Products and then returned to Natera and that Natera did not invent the method of amplifying DNA employed in the AMP process." D.I. 196, 13; Ex. 433-3, Ex. 16, 6:23-7:24 ("Q: And you understand that you're here to testify on Topic 50...You're prepared to testify on that? A: Yes.").

Cir. 2013). Defendants have failed to show how a ministerial change in inventorship, without more, is but-for material. Defendants appear to suggest that inventorship is *per se* material, D.I. 441, 24, but even “[a]n error in determining inventorship is not by itself inequitable conduct.” *Pro-Mold & Tool Co. v. Great Lakes Plastics*, 75 F.3d 1568, 1576 (Fed. Cir. 1996). None of the cases cited by Defendants provide otherwise. In *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, an ex-employee claimed that he should have been named the inventor, the sole named inventor had not contributed to the invention, and no party sought to correct inventorship under Section 256. 607 F.3d 817, 824, 828 (Fed. Cir. 2010). By contrast, none of the current and previously named inventors of the Natera cfDNA Patents dispute inventorship.

Nor does *Egenera, Inc. v. Cisco Sys., Inc.* support Defendants’ position. 972 F.3d 1367 (Fed. Cir. 2020). Rather, it supports Natera’s. In that case, the district court did *not* find inequitable conduct even where a change of inventorship was found to be “a considered act that is unlikely to qualify as an omission ‘through error.’” *Id.* at 1376. As the court explained, “Our precedent recognizes that a patent cannot be invalidated if inventorship can be corrected instead.” *Id.* (citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350 (Fed. Cir. 1998); 35 U.S.C. § 256(b)).<sup>5</sup>

Defendants have failed to adduce *any* evidence that a ministerial change in inventorship is but-for material such that the cfDNA Natera patents would not have issued, much less advanced a clear and convincing showing. Defendants’ defense founders on this element.

Defendants also fail to adduce *any* evidence that intent to deceive the PTO is the only reasonable inference that can be reached from the ministerial change in inventorship. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011). No reasonable

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<sup>5</sup> Further, Federal Circuit precedent “provides that ‘error’ in § 256 includes ‘all varieties of mistakes—honest and dishonest’—rather than only unintentional inaccuracy.” *Egenera*, 972 F.3d at 1376 (citing *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1554–56 (Fed. Cir. 1997)).

jury would find a clear intent to deceive the PTO as the only reasonable inference when it is undisputed that every current and previously named inventor *agreed* under oath to the change in inventorship. Defendants attempted to, but were unsuccessful in, obtaining any evidence that could call into question the inventorship declarations. Perhaps recognizing this unsurmountable evidentiary hurdle, Defendants attempt to manufacture fact disputes based on inventors' alleged failure to "justify their inventorship oaths" (D.I. 441, 25). But there are no fact disputes—the inventors confirmed the veracity of their Declarations when asked and there is nothing to undermine that testimony. D.I. 441, 26 (Inventor Dr. Demko: "I rely on our IP team to do proper diligence, and I - if I have no reason to object to their conclusions, then I go along with it."). Defendants cannot avoid summary judgment by pointing to a lack of evidence on an issue where they bear the burden. *Cordance*, 631 F. Supp. 2d at 488 ("If the moving party has demonstrated an absence of material fact, the nonmoving party must then ""come forward with specific facts showing that there is a genuine issue for trial."") (quoting Fed. R. Civ. P. 56(c)). Natera's invocation of privilege because of Defendants' failure to ask proper questions is not evidence of intent to deceive. D.I. 441, 27.<sup>6</sup> Summary judgment is appropriate.<sup>7</sup>

## **2. No Inequitable Conduct Based on Alleged Failure to Disclose Litigation Documents to the PTO**

Defendants' second set of inequitable conduct allegations are based on alleged failure to present information in a certain *format* (e.g. "easy to follow table" format or conclusory Section 103 allegations), not that the underlying information was not disclosed to the Patent Office. There

<sup>6</sup> Indeed, the Court rejected Defendants' complaint about Natera's invocation of privilege, explaining "the Court is not persuaded anything improper occurred," noting "Defendants' strategy of asking broad questions implicating legal issues and privilege." D.I. 388.

<sup>7</sup> *F'Real Foods, LLC v. Hamilton Beach Brands, Inc.*, No. 16-41-CFC, 2019 WL 1747550, at \*1 (D. Del. Apr. 18, 2019) is distinguishable. In that case, the parties disputed the meaning of an ex-employee's writing in a document to evaluate whether the ex-employee was an unnamed inventor. No such disputed evidence is at issue here.

is no requirement that information be disclosed in a certain format and Defendants point to none. Specifically, Defendants identify two types of information that Natera allegedly failed to disclose to the Patent Office: (a) supposed admissions about “routine” and “conventional” techniques in a “easy to follow table”; and (b) Defendants’ Section 103 allegations in their Answers. D.I. 441, 28-29. Neither is material.<sup>8</sup>

The supposed admissions about “routine” and “conventional” techniques were disclosed in the *Illumina* and *CareDx* litigation documents Natera submitted to the Patent Office.<sup>9</sup> See D.I. 134, ¶ 145 (identifying the several *Illumina* and *CareDx* litigation documents Natera had disclosed to the Patent Office, including Natera’s Answer and Invalidity Contentions in the *Illumina* litigation and, Natera’s motion to dismiss and associated exhibits in the *CareDx* litigation). Defendants do not dispute the content of these documents or that these litigation documents were disclosed to the Patent Office. D.I. 441, 28. Defendants instead contend that Natera did not disclose the “easy to follow table” of Natera’s supposed admissions in Defendant ArcherDX’s Rule 12(c) motion. D.I. 441, 29. But the supposed admissions, which are excerpts from the ’814 Patent (which was before the Patent Office) and statements about the routine and conventional nature of techniques from the *Illumina* and *CareDx* litigations—were already disclosed to the Patent Office. The Patent Office was aware of the *Illumina* and *CareDx* litigations, was apprised of the position Natera had taken about the invalidity of the *Illumina* patent and the state of the art,

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<sup>8</sup> Defendants do not address the lack of materiality of documents relating to Section 101 and Section 112 issues. D.I. 432, 20-21.

<sup>9</sup> In its Answer in the *Illumina* litigation submitted to the Patent Office, Natera stated, “The ’831 patent also does not contain an inventive concept because the selective enrichment of DNA sequences and successive rounds of amplification using primers are *routine* and *conventional*.<sup>10</sup>” Ex. 41, ¶ 55 (emphasis added). Likewise, in its motion to dismiss in the *CareDX* litigation submitted to the Patent Office, Natera repeatedly discussed the routine and conventional nature of techniques in the context of CareDx patent. Ex. 35, 12 (“disclosing the *routine and conventional nature of the techniques*” recited in CareDX patent) (emphasis added).

and was informed about Natera’s position on the invalidity of the CareDx patent. D.I. 433-4, ’220 Patent, 9, 11. Defendants have adduced no evidence that the examiner would not have issued the ’220 Patent but for the “easy to follow table” in the Rule 12(c) motion, when the examiner had the underlying information. *See Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) (“An applicant is not required to tell the PTO twice about the same prior art, on pain of loss of the patent for inequitable conduct.”).

As for the Section 103 allegations in Defendant ArcherDX’s Answers that Defendants claim Natera failed to disclose (D.I. 441, 28), it is undisputed that the references underlying the Section 103 allegations were before the Patent Office. *Fiskars*, 221 F.3d at 1327 (“an applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.”). Defendants do not adduce any evidence that but for Defendants’ self-serving Section 103 allegations in the Answers, the examiner would not have issued the ’220 Patent, even though the references were disclosed to the examiner.

Finally, Defendants have not adduced *any* evidence to show a clear deceitful intent by Dr. Rabinowitz as the only reasonable inference to be reached from the alleged non-disclosure of certain litigation documents. D.I. 441, 29-30. In fact, Defendants have failed to proffer *any* evidence that Dr. Rabinowitz even knew about the Rule 12(c) brief, Archer’s Answers or their contents, let alone any purported materiality of the alleged information buried in these documents or any intent to deceive the Patent Office. Another court in this District has rejected finding specific intent even when the reference was known to be material and was not disclosed. *Bayer Cropscience AG v. Dow Agrosciences LLC*, No. 1:10-CV-1045, 2012 WL 1253047, at \*4- 5 (D. Del. Apr. 12, 2012). Here, the facts are even more non-existent. This is a text-book example of alleging inequitable conduct “on the slenderest grounds,” a practice characterized by the courts as

“an absolute plague.” *Therasense*, 649 F.3d at 1289. Defendants have failed to carry their clear and convincing burden of establishing inequitable conduct. Summary judgment of no inequitable conduct is warranted.

#### **D. DEFENDANTS HAVE FAILED TO ESTABLISH INVALIDITY BASED ON IMPROPER INVENTORSHIP**

As an initial matter, even if there was an error in inventorship (there is none), correction, not invalidation is the remedy. *Egenera*, 972 F.3d at 1376 (“A patent cannot be invalidated if inventorship can be corrected”). Defendants do not dispute this. Nor do Defendants dispute that under Section 256 as amended by the AIA, this is so even if the error in inventorship was made with deceptive intent. *Id.* at 1376-77. None of the cases Defendants cite provide otherwise. The courts either did not permit an inventorship defense (*Drone Techs., Inc. v. Parrot S.A.*, 838 F.3d 1283, 1293 (Fed. Cir. 2016)) or the Section 256 correction was not invoked<sup>10</sup> or would have been futile because the claim had been rendered invalid as obvious.<sup>11</sup> Thus, any insinuation by Defendants about a finding or inference of invalidity based on inventorship when correction is available is incorrect.<sup>12</sup> Summary judgment is warranted as a matter of law for this reason alone.

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<sup>10</sup> *Bos. Sci. Corp. v. Johnson & Johnson*, 550 F. Supp. 2d 1102, 1114 (N.D. Cal. 2008) (“the Court notes that BSC could have invoked 35 U.S.C. § 256 to correct the inventorship of the Kastenhofer patents, . . . , but has not done so.”); *Plastipak Packaging, Inc. v. Premium Waters, Inc.*, No. 20-CV-098-WMC, 2021 WL 3675151, at \*9, n.15 (W.D. Wis. Aug. 19, 2021) (“plaintiff has not sought a correction”); *Magnetar Techs. Corp. v. Six Flags Theme Parks, Inc.*, No. CV 07-127-LPS-MPT, 2014 WL 547712, at \*9 (D. Del. Feb. 7, 2014) (Plaintiff did not seek a correction).

<sup>11</sup> *Auxilium Pharm., Inc. v. Watson Labs., Inc.*, No. CIV.A. 12-3084 JLL, 2014 WL 9859224, at \*34 (D.N.J. Dec. 16, 2014) (noting that correction under § 256 was available but futile because claim 3 of the patent had been found invalid as obvious).

<sup>12</sup> Defendants’ statements questioning the availability of Section 256 to Natera to make corrections or the possibility of judicial estoppel have no basis and are nothing more than speculation. D.I. 441, 15; *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 1512334, at \*4 (E.D. Tex. Apr. 27, 2017) (“the defendants could win on their inventorship defense, but Allergan could move to correct inventorship under section 256 and, if prevailing on that motion, move to vacate the judgment of invalidity. . . . So, the defendants could prove incorrect inventorship but still be liable for infringement following an order correcting the error in the naming of inventors.”)

Moreover, Defendants cannot succeed in their inventorship defense because Defendants have failed to show nonjoinder or misjoinder. Defendants contend that Dr. Lacroix should be named as an inventor of the cfDNA Patents because he allegedly invented Natera's primer design technique. D.I. 441, 17-20. But this makes no sense because, according to Defendants, this primer design technique is *not covered* by the claimed methods. D.I. 430, Sections F & G. If the claims of the cfDNA Patents do not require Natera's primer design technique, whether Dr. Lacroix invented said techniques has no bearing on whether he should be named as an inventor of the cfDNA Patents.<sup>13</sup>

Defendants also contend that Natera does not explain why Dr. Lacroix is not an inventor of the cfDNA Patents. D.I. 441, 18. That burden does not rest on Natera.<sup>14</sup> In any event, Dr. Lacroix could not have been an inventor because he did not join Natera until spring 2012 (a fact Defendants concede (D.I. 441, 18)), *after* the patent priority date of November 18, 2011.

Defendants also founder on the corroboration requirement to show inventorship. D.I. 442, 23-26. Defendants attempt to cure this fatal failure by identifying allegedly "corroborating evidence" for the first time in their opposition brief,<sup>15</sup> but that argument cannot withstand scrutiny.

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<sup>13</sup> Defendants bear the burden of showing misjoinder or nonjoinder. Defendants cannot rely on a footnote to reserve their right to argue about mysterious purported inventors—individuals that Defendants do not even name. See D.I. 441, 17, n.5. This is improper.

<sup>14</sup> Defendants, not Natera, bear the burden of proving any alleged improper inventorship and inventorship of issued patents is presumptively deemed accurate. *Hess v. Advanced Cardiovascular Sys. Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997) (quotation omitted).

<sup>15</sup> Defendants have waived this argument by not identifying it during discovery. *XpertUniverse, Inc. v. Cisco Sys., Inc.*, No. 09-157-RGA, 2013 WL 867640, at \*10 (D. Del. Mar. 8, 2013) ("XU's new theories in opposition to summary judgment are untimely and not supported by any record evidence; it is unclear what 'business opportunities' XU is even alleging. One reasonable conclusion is that XU proposed these new theories to survive summary judgment, as opposed to in response to the natural course of litigation and discovery. They will not serve to save Counts XIII, XIV, XV, or XVI from being superseded by XU's CUTSA claim (Count V). Cisco's motion is granted on Counts XIII, XIV, XV, and XVI."); *Malico Inc. v. Cooler Master USA*, No. C 11-4537-RS, 2013 WL 4482503 (N.D. Cal. 2013) ("a party's own tardiness in creating a key piece of

Defendants contend that: (1) a 2013 Natera patent application publication (Ex. CC); (2) Natera documents (Exs. DD, FF-HH); and (3) testimony of Natera scientists Mr. Dodd, Dr. Hill and Mr. Wong corroborates that Dr. Lacroute should have been named an inventor of the cfDNA Patents. D.I. 441, 18-20. But these documents merely confirm that Dr. Lacroute worked on *Natera's* primer design technique *after* the priority date of November 18, 2011. The 2013 patent application publication and the Natera documents were filed or created *after* November 18, 2011.<sup>16</sup> The testimonies do not provide otherwise. That Natera's '220, '172, and '814 Patents also claim the benefit of the 2013 application (in addition to the 2011 priority application) is of no moment—it simply reflects that new matter added in the 2013 application is also included in the specification of the issued '220, '172, and '814 Patents. In sum, Defendants' "corroborating" evidence only corroborates that Dr. Lacroute was correctly *not* listed as an inventor of the cfDNA Patents.

Similarly, Defendants' "corroborating evidence" for Dr. Ryan's work does not support their arguments for misjoinder. D.I. 433-3. Defendants point to certain documents cited in Natera's interrogatory response and focus on Dr. Ryan's lack of recall about these documents, which were generated over 12 years ago, to argue that Dr. Ryan should not be named an inventor. D.I. 441, 21-22. But "forgetfulness" is precisely one of the reasons courts require corroborating evidence rather than relying on inventor testimony alone to prove invention. *See Finnigan Corp. v. United States Int'l Trade Comm'n*, 180 F.3d 1354, 1366 (Fed. Cir. 1999) ("The Supreme Court recognized over one hundred years ago that testimony concerning invalidating activities can be 'unsatisfactory' due to 'the forgetfulness of witnesses, their liability to mistakes, their proneness

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evidence on which it intends to rely in support of a dispositive motion does not excuse its failure to satisfy its disclosure obligations.'").

<sup>16</sup> Ex DD is a document dated "8 April 2013" and Ex. FF-HH are email correspondences that were sent in May and June 2012.

to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury.””) (quoting *The Barbed-Wire Patent*, 143 U.S. 275, 284 (1892)). Nothing in the identified documents themselves indicate that Dr. Ryan should not be named an inventor and Defendants point to none. Defendants have failed to meet their clear and convincing burden of proving improper inventorship. *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1380 (Fed. Cir. 2000) (finding that the defendant did not sustain its inventorship burden where defendant “relied entirely on [the inventor’s] lack of precision in defining her invention in the course of her deposition and the DX13 prototype, rather than introducing clear and convincing evidence that someone else was the true inventor.”).

Other than the above defunct “corroborating” evidence,<sup>17</sup> Defendants adduce no other evidence beyond select inventor testimonies devoid of context. D.I. 441, 20-21. Inventor testimony alone without any corroborating evidence cannot sustain an inventorship defense as a matter of law. *Beriont v. GTE Labs. Inc.*, 601 Fed. Appx. 937, 939-940 (Fed. Cir. 2015); *Univ. of Colorado Foundation, Inc. v. Am. Cyanamid Co.*, 342 F.3d 1298, 1308 (Fed. Cir. 2003); *Trovan, Ltd. v. Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002).

Defendants miss the mark by arguing they will present additional evidence at trial. D.I. 441, 23. Defendants are required to come forward with a clear showing in response to this motion. *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 359 (D. Del. 2019) (“An assertion that a fact . . . is genuinely disputed must be supported [] by citing to ‘particular parts of materials

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<sup>17</sup> Defendants attempt to transfer the burden of proving inventorship to Natera, by arguing that Natera does not discuss a single corroborating document in its moving brief. D.I. 441, 22. Natera does not need to. Regardless, Natera included detailed corroborating evidence as an exhibit. D.I. 433-3. Inventors are presumed to be named correctly and Defendants bear the burden of proving otherwise. D.I. 432, 23. Attorney arguments and rhetoric cannot compensate for lack of evidence or raise genuine issue of disputed facts.

in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials””) (quoting Fed. R. Civ. P. 56(c)(1)(A) & (B).). Vague appeals of additional evidence at trial, or faulty expert testimony, is wholly insufficient to meet their clear and convincing burden of proof. Summary judgment is appropriate.

#### **E. THE ASSERTED PATENTS CLAIM WHAT THE APPLICANTS REGARDED AS THEIR INVENTIONS**

Defendants fail to meet their heightened burden to show that the asserted patents do not claim what the applicants regarded as their inventions. It is undisputed that: (1) the claimed methods are disclosed in the specification, including Figure 6, as Defendants’ expert admits (*see also* D.I. 442, 25-28); (2) nowhere in the patent do the applicants state that the claimed methods are not their inventions; and (3) to the contrary, the patents expressly refer to the claimed methods as inventions. D.I. 432, 27-28. This legally should end the inquiry.

Defendants, however, attempt to redefine the claimed invention as prior art “nested PCR.”<sup>18</sup> D.I. 441, 35-36. The claims are not directed only to “nested PCR,” but to novel methods of targeted amplification of DNA with nested PCR being just one limitation in these methods. If the claimed inventions were only prior art nested PCR, surely Defendants would have identified prior art references teaching the entire claimed method. They have not.

Defendants’ argument that Natera’s claims allegedly do not address primer dimer problems in multiplex PCR, D.I. 441, 31-32, does not raise any genuine issue of disputed fact. Defendants only reference out-of-context select inventor testimonies as evidence. D.I. 441, 31-32. Such inventor testimonies “obtained in the context of litigation, should not be used to invalidate issued

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<sup>18</sup> To the extent Defendants are making this “did not claim what they regarded as invention” argument with respect to the ’708 Patent, the claims of the ’708 Patent do not even recite “nested PCR.”

claims under section 112, paragraph 2.” *Solomon*, 216 F.3d at 1380.

Further, “[t]he determination whether a claim recites ‘the subject matter which the applicant regards as his invention’ . . . ‘is a legal conclusion that is drawn from the court’s performance of its duty as the construer of patent claims.’” *Id.* at 1377 (quotations omitted).<sup>19</sup> As Defendants concede, they made the “essential” concept argument to the Court during claim construction, but the Court rejected it. D.I. 441, 33; *see also* D.I. 243, 6 (rejecting Defendants’ construction of the claimed inventions as only encompassing those that “avoid primer side products”). If there were truly an “irreconcilable contradiction” between the purportedly “essential” concept disclosed in the specification but not included in the claims as Defendants’ argue, D.I. 441, 33, the Court, as the “construer of patent claims,” would have resolved the issue in Defendants’ favor, not Natera. But it did not. Natera claimed what it invented. *See Ancora Techs. Inc. v. Apple, Inc.*, 744 F.3d 732, 739 (Fed. Cir. 2014) (“Ancora embraces the claim language’s clear, ordinary meaning, and . . . we do not think that the specification and prosecution history establish that the applicants regarded their invention as something contrary to that meaning.”). Defendants’ repeated attempts to revisit the Court’s claim construction ruling under different guises should be rejected. Summary judgment is appropriate.

#### **F. THE ASSERTED CLAIMS OF THE ’708, ’814 AND ’220 PATENTS ARE NOT INDEFINITE**

Bereft from Defendants’ opposition is any evidence or argument not previously considered and deemed insufficient by this Court. The Court gave Defendants an opportunity to develop the record on indefiniteness, but Defendants have not done so.

##### **1. The ’708 Patent Claims Are Not Indefinite**

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<sup>19</sup> After identifying only the *Allen Eng’g* case as legal basis for their position during discovery, Defendants identify *Solomon v. Kimberly-Clark Corp* for the first time in their opposition. But *Solomon* is equally unhelpful to Defendants’ position.

With no new evidence in hand, Defendants attempt to rewrite the record about Owczarzy: that (a) Natera cited Owczarzy 2008 during claim construction only for the proposition that Primer3 was a less costly surrogate; and (b) “Natera never argued that the patent discloses a version of Primer3 that includes Owczarzy or that a skilled artisan would even use the Owczarzy option given such a Primer3 version.” D.I. 441, 3, n.1. As shown below, Natera’s *Markman* hearing slide identifying Owczarzy 2008 with specific evidentiary citations belies Defendants’ arguments:

**A Melting Temperature Of The At Least 2 Primers**

**The High Correlation Continued To Improve Well Before The Priority Date**

Using the algorithm of Figure 9 with the correction formulas presented herein, the  $T_m$  can be predicted within an average accuracy of 1°C. Earlier models are less accurate and in some cases lead to large errors (>10 °C).

**Dr. John Quackenbush**  
Expert Witness

"The 2008 Owczarzy reference contained formulas to correct that were later incorporated into the Primer3 program as of 2014 that could identify the  $T_m$  "within an average accuracy of 1°C[.]" supporting the reliability of the patent-taught  $T_m$  calculation methods."

Ex. A-2, Quackenbush Suppl. Decl., ¶ 30

*See also* D.I. 177, 73-74 (“*Primer3 tool available as of the ‘708 Patent’s 2014 priority date* is quite consistent, with at most an approximate 1 degree C difference from the more precise, but costly, empirical UV approach applying the same conditions. (Ex. A-2, *Quackenbush Suppl. Decl.*, ¶¶ 25, 30; Ex. B-32, *Owczarzy 2008*).”) (emphasis added).

Defendants’ expert Dr. Cooper, did not address Owczarzy 2008 in his expert reports and candidly admitted that he had not reviewed Owczarzy 2008 in rendering his opinions. D.I. 432, 32-33. Defendants’ belated arguments to remedy their failure are too late and without merit.

The patent discloses use of the Owczarzy formula as set forth in Owczarzy 2008, contrary

to Defendants' contention. D.I. 441, 4. The patent incorporates by reference the Primer3 program. (D.I. 433-2, '708 Patent, 235:52-54 ("(the world wide web at primer3.ut.ee/primer3web\_help.htm#PRIMER\_TM\_FORMULA, which is *hereby incorporated by reference in its entirety*)") (emphasis added). This webpage, which is incorporated by reference in its entirety, sets forth the Primer3 manual that, as of February 1, 2014, expressly incorporates the Owczarzy 2008 formula, as shown by the Internet Wayback machine. Ex. 37, 15 ([https://web.archive.org/web/20140201065817/https://primer3.ut.ee/primer3web\\_help.htm](https://web.archive.org/web/20140201065817/https://primer3.ut.ee/primer3web_help.htm)). By incorporating the website, the '708 Patent expressly teaches Primer3 using the Owczarzy 2008 formula.

The Primer3 manual teaches the use of the Owczarzy 2008 formula, contrary to Defendants' argument. D.I. 441, 4-5. The Primer3 manual provides, "A value of 2 *directs primer3 to use* the salt correction formula in the paper [Owczarzy . . . (2008)."]. Ex. 37, 15 (emphasis added). While Primer3 also includes options of "0" and "1" that specify the other salt correction method, nowhere does the Primer3 manual "tell the user not to use" option "2," as Defendants argue. D.I. 441, 5. Defendants obfuscate the distinction between the options for *salt corrections* vis-à-vis the melting temperature calculation methods and appear to conflate the two. A POSA would know to use the recommended SantaLucia melting temperature calculation method *and* the appropriate salt correction formula, such as using the Owczarzy formula "when divalent cations [(salt)]are present." D.I. 441, 5 (quoting Primer3 manuals); D.I. 433-2, '708 Patent, 236:1-10.

Natera's expert's testimony further refutes Defendants' attorney argument about Primer3 allegedly teaching to not use Owczarzy:

- "By the priority date of the patent, the optimal parameters and methods for calculating the primer Tm's methods for adjusting for reaction conditions (e.g., . . . mono-valent and di-valent salt concentration) *were known and included into the Primer3 program.*" Quackenbush Suppl. Markman Decl, ¶ 29 (emphasis added).

- “Even the later 2001 and 2008 Dr. Boehm references contained parameters (*e.g.*, magnesium or dNTP concentrations) and described methods that corrected for these; these parameters were also incorporated into the Primer3 program. . . . Furthermore, *the 2008 Owczar[z]y reference contained formulas to correct that were later incorporated into the Primer3 program as of 2014* that could identify the Tm “within an average accuracy of 1°C[,]” supporting the reliability of the patent-taught Tm calculation methods. (Def. Ex. 41, Owczarzy 2008).” Quackenbush Suppl. Markman Decl, ¶ 30 (emphasis added).
- “My understanding is that the patent specification covers *using Primer3 with the most recent settings as of the date of this -- of this patent* to -- to make a calculation of it . . . . And . . . the Primer3 methodology is highly accurate and concordant with the melting temperature method done physically.”). Ex. 40, Spellman Tr. 219:15-23 (emphasis added).

Thus, Defendants’ argument that Natera lacks admissible evidence rings hollow.<sup>20</sup>

Defendants repeat the same failed arguments pertaining to calculating melting temperature of a primer longer than 35 nucleotides—they point to Natera using the Bolton and McCarthy method during the prosecution of a different patent. D.I. 441, 7-8. But they have no rebuttal to Natera’s evidence that a POSA would use the UV method in those situations. In any event, Defendants already made this argument which the Court deemed unconvincing. D.I. 442, 15-16.

## **2. The Claim Term “Sequencing Tag” Does Not Render the Asserted ’814 and ’220 Patents Indefinite**

Defendants do not dispute that they have failed to adduce evidence beyond the record found wanting by this Court at the *Markman* stage. Instead, they conjure up fact disputes when none exist. D.I. 441, 8-11. Five of Dr. Cooper’s alleged six “points and evidence” (D.I. 441, 9) were found insufficient by this Court to show indefiniteness. D.I. 432, Section E. Dr. Cooper’s sixth point about inventor testimony fares no better. The inventors merely testified that they needed to evaluate the patent specification to understand the meaning of sequencing tag. D.I. 442, 35-36. In

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<sup>20</sup> Defendants’ argument that Natera inventors have no foundation to provide fact testimony about Owczarzy 2008 is pure speculation. D.I. 441, 6. Defendants did not question the inventors about the Owczarzy 2008 reference. Thus, Defendants have no basis to opine about Natera inventors’ knowledge about Owczarzy 2008.

any event, inventor testimony “obtained in the context of litigation, should not be used to invalidate issued claims under section 112, paragraph 2.” *Solomon*, 216 F.3d at 1380.

Taking Dr. Spellman’s testimony about “sequence tag” and “sample index” out-of-context, Defendants manufacture a factual dispute on alleged inconsistency between Dr. Spellman’s testimony and Natera’s position. D.I. 441, 9-11. There is no inconsistency when Dr. Spellman’s testimony is viewed in context. Dr. Spellman was provided a definition for “sequence tag” from a non-Natera “Quake” patent (“DNA sequence of sufficient length that it may be assigned specifically to one of chromosomes 1-22, X or Y”) (Ex. BB at 250:2-251:7) which is different from the Court’s construction of “sequencing tag” (“a nucleic acid sequence introduced to carry out the process of high throughput sequencing”). When questioned if the so-defined “sequence tag” was equivalent to “sequencing tag as used in claim 1 of the ’220 Patent” (*i.e.*, the court’s construction of “sequencing tag”), Dr. Spellman testified that they are not equivalent. D.I. 441, 10 (citing Ex. BB at 250:19-251:13). This is entirely consistent with Natera’s position and Dr. Spellman’s opinion that “a sequence tag can be a sequencing tag sold by a sequencing platform company.” Ex. 39, Spellman Rpt., ¶ 334.

Likewise, Dr. Spellman opined and testified that sample index can be part of a sequencing tag. Ex. 40, Spellman Tr. 255:1-5 (“Q. Can a sample index on its own be a sequencing tag? THE WITNESS: If it’s introduced for the purpose of carrying out sequencing, yes.”) (attorney objection removed); Ex. 39, Spellman Rpt., ¶ 336. This is consistent with Natera’s position that “a sample index can be part of, or an element of, the sequencing tag.” D.I. 185, 77:7-13. That a sample index need not always be a sequencing tag is also consistent with Dr. Spellman’s testimony cited by Defendants (D.I. 441, 11 (citing Ex. BB at 259:4-21, 261:15-262:3)), and Natera’s position. Defendants’ manufactured factual dispute is not “genuine,” *i.e.*, “evidence [] such that a reasonable

jury could return a verdict for the nonmoving party.” *Morphosys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 359 (D. Del. 2019) (quotation omitted). Summary judgment of no indefiniteness is warranted.

## II. DAUBERT MOTION ARGUMENTS

### A. MR. KELLEY’S PROSECUTION LACHES OPINIONS SHOULD BE EXCLUDED IN ITS ENTIRETY

Mr. Kelley’s opinion is that of a patent law expert. Judges in this district have a “well-established practice of excluding the testimony of legal experts, absent extraordinary circumstances.” D.I. 432, 37. The two cases Defendants cite in their opposition brief do not hold otherwise, and in fact, confirm that such patent law expert testimony has been limited at most to explaining general practices and procedures employed by the PTO in examining or reexamining patents. D.I. 441, 47 (citing *Sonos, Inc. v. D&M Holdings, Inc.*, 297 F. Supp. 3d 501, 511 (D. Del. 2017); *Purewick Corp. v. Sage Prods., LLC*, No. 19-1508, 2021 WL 2593338, at \*1 (D. Del. June 24, 2021)). Mr. Kelley is not opining on general practices and procedures employed by the PTO in examining patents and admitted as such in acknowledging that he does not discuss or even cite to the Manual of Practice Examining Procedure (“MPEP”).<sup>21</sup> D.I. 432, 38.

The majority of Mr. Kelley’s testimony is not simply “devoted to walking through the prosecution history of the cfDNA Patents and dozens of related applications” as Defendants would have the Court believe. D.I. 441, 47.<sup>22</sup> Rather, and as stated in Natera’s opening brief, Mr.

<sup>21</sup> Defendants attempt to minimize the relevance of the MPEP (D.I. 441, 48), but as Mr. Kelley acknowledges, the MPEP includes procedures that patent examiners are required or authorized to follow. D.I. 432, 38. That it may not be a binding source of law is irrelevant. It is the manual for patent examining *procedure*, and procedure is what Mr. Kelley is allowed to opine on, not legal interpretation.

<sup>22</sup> Even if a summary of the prosecution history and Defendants’ product development were relevant, they should be admitted into evidence through a competent witness or through an expert who is offering an admissible opinion based on them, such as Defendants’ validity expert. Mr. Kelley has no technical expertise in the relevant art to offer such opinions.

Kelley's testimony is that of a patent law expert "that add[s] a party's particular spin to disclosures in the prosecution" which "have regularly been excluded." *Purewick*, 2021 WL 2593338, at \*1. In *Purewick*, Sage's patent law expert "walk[ed] through certain facts in the prosecution history but [did] so by offering Sage's spin on what happened, essentially making arguments that Sage's litigation counsel should make – not an expert on the stand." *Id.* at \*2. The court further noted that Sage's patent law expert also included witness testimony "further straying from this being a simple factual 'walk-through' of the prosecution and making it much more of a lawyer's argument" and "inappropriate for an expert witness." *Id.* Similar to Sage's patent law expert in *Purewick*, Mr. Kelley's opinions are untethered to PTO practice and procedure and simply state Defendants' version of the facts and conclusions of alleged delay.<sup>23</sup> D.I. 432, 37-40.

Defendants argue that Mr. Kelley's opinions on purportedly "unusual" aspects of the prosecution history are based on his knowledge of PTO practice and procedure. D.I. 441, 47. That argument lacks merit. There are no statutory or patent office procedural limitations on the length of the applications, size or complexity of priority claims, or practice of filing multiple applications, and Mr. Kelley points to none. D.I. 433-3, Ex. 24 ¶¶ 98-101, 102-109. Tellingly, Mr. Kelley admitted that he is not aware of any evidence that the examiner expressed any "confusion by the number of priority claims" or that the asserted cfDNA Patents were "too lengthy." Ex. 38, Kelley Tr., 113:17-114:18.

Defendants argue that Mr. Kelley "applies his expertise" (D.I. 441, 47-48), but Mr. Kelley's opinions on unreasonable or unexplained delay and intervening rights do not touch upon

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<sup>23</sup> Mr. Kelley renders an opinion of unreasonable delay, precisely the province of the court. *Cordance*, 631 F. Supp. 2d at 489 ("The issue before the court, therefore, is whether Cordance's delay in prosecuting the '710 patent, as one of a series of related patents, was unreasonable and unexplained.")

PTO practice and procedure, and further, improperly interpret select snippets of deposition testimony of Natera’s witnesses and other documents. D.I. 432, 37-40; *Purewick*, 2021 WL 2593338, at \*1 (Sage’s patent law expert offered conclusions about whether the patents were subject to an on-sale bar by interspersing documents, contentions and testimony and discussed “Purewick’s motivation in taking purported ‘unreasonable’ positions or doing ‘unreasonable’ things,” and the court held that “none of this is appropriate as expert testimony.”). As the court in *Purewick* held, Defendants “may not use a ‘patent expert’ on the stand to make arguments that its litigation counsel should be making.” *Id.*

Mr. Kelley’s prosecution laches opinions are an improper attempt to offer a lawyer’s interpretation of law and facts; he should not be permitted to act as a conduit to make arguments that Defendants’ counsel should make to the Court or a jury. In line with the consistent practice in this District, the Court should exclude Mr. Kelley’s prosecution laches opinions in its entirety. Defendants have presented no “extraordinary circumstances” to hold otherwise.

**B. DR. COOPER’S INVENTORSHIP OPINIONS SHOULD BE EXCLUDED IN ITS ENTIRETY**

“[I]nventorship is a claim-by-claim question” because “who should be listed on the face of a patent may vary depending on what, exactly, is claimed and what, exactly, a court determines the claim scope to be.” *Egenera*, 972 F.3d at 1376. It is undisputed that Dr. Cooper did not evaluate the contribution of the inventors to each claim. Vague reference to how an issue is connected to a claim (D.I. 441, 45) falls far short of the required claim-by-claim analysis. Dr. Cooper’s inventorship opinions are plainly legally deficient.

Dr. Cooper’s inventorship opinions are also factually unsupported, legally flawed, and unreliable. The entirety of Dr. Cooper’s opinion rests on the flawed premise that he can ascertain inventorship based solely on his interpretation of whether select snippets of deposition testimony

taken out of context suggest that a given individual worked on “techniques for target loci selection and primer design to avoid primer dimers” in multiplex PCR.<sup>24</sup> D.I. 432, 24-26, 40-41. Defendants do not dispute that Dr. Cooper “relied primarily on inventor testimony” or that he did not rely on any corroborating evidence. D.I. 441, 46. It is well-established that “[e]ven the most credible inventor testimony is *a fortiori* required to be corroborated by independent evidence.” *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1171-72 (Fed. Cir. 2006); *Apator Miitors APS v. Kampstrup A/S*, 887 F.3d 1293, 1295 (Fed. Cir. 2018) (“when a party seeks to prove conception through an inventor’s testimony the party must proffer evidence, ‘in addition to [the inventor’s] own statements and documents,’ corroborating the inventor’s testimony”). Once again, Defendants failed to address or distinguish any of this controlling case law in their opposition brief. Without corroborating evidence, Dr. Cooper’s citation to out-of-context, select inventor testimony is unreliable, unhelpful to the trier of fact and legally insufficient. In short, Dr. Cooper’s inventorship opinion is nothing more than a conduit for Defendants’ self-serving spin on select witness testimony and should be excluded in its entirety.

### **III. CONCLUSION**

In light of the above, Natera’s motion for partial summary judgment and to preclude certain expert testimony should be granted.

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<sup>24</sup> As stated in Natera’s moving brief, Defendants are improperly attempting to backdoor in their rejected claim construction position that the asserted claims should be limited to primer design that avoid primer dimers and summary judgment that the asserted claims are not invalid for alleged failure to set forth “what the applicants regarded as the invention” is appropriate. D.I. 432, 26-29. Dr. Cooper’s inventorship opinions rest on this faulty presumption.

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February 25, 2022

**CERTIFICATE OF SERVICE**

I hereby certify that on February 25, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 25, 2022, upon the following in the manner indicated:

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